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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,515	10/16/2003	Brian L. Newton	1600/162	5231
2101	7590	10/05/2005		
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			EXAMINER MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,515

Applicant(s)

NEWTON ET AL.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6-8, 10, 13, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Purdy et al (5,535,771).

3. Purdy discloses a medical valve (10) having an open mode to permit fluid flow and a closed mode to prevent fluid flow and a closed mode to prevent fluid flow comprising a body (figure 4) forming an interior (fig 4), a proximal port (70) and a distal port (64), the interior having a fluid channel between the proximal port and the distal port (abstract lines 3-4) and a valving element (40) within the interior of the body controlling fluid flow between the proximal and distal ports, the valving element including a resilient member (42) and a plug (57), the resilient member forming a variable volume fluid chamber (31) within the interior of the body, the fluid chamber being at least a part of the fluid channel (abstract lines 7-10), the plug cooperating with the resilient member to provide an internal seal (57 in conjunction with 42 prevents any fluid from entering into the resilient structure and instead allows for it to be directed around into the fluid chamber and channels formed by the outer surface of the resilient member) within the interior of the body, the internal seal being spaced from the proximal port (70), the plug being capable of radially expanding the resilient member when the valve transitions

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from the closed mode to the open mode (while the drawings do not indicate radial expansion, it is inherent that a resilient material such as silicone rubber (col 6, lines 60-67) will radially expand upon compression), the fluid chamber to have a larger volume when in the open mode than when in the closed mode (when resilient member 42 is pushed down by plug 57, a flow path is opened, such flow path increasing the volume of fluid chamber 31), the radial expansion also causing the fluid channel to have a larger volume when in the open mode than when in the closed mode (when resilient member 42 is pushed down by plug 57 and radially expands, a flow path is opened, and the fluid channel will inherently have a larger volume in open mode).

With regards to claim 6, Purdy et al discloses the interior including a stop (32), the plug being capable of longitudinally moving distally within the interior to contact the stop (47), the plug being capable of radially expanding the resilient member after the plug contacts the stop (once the plug 57 contacts the stop 47, it will push down on resilient member 42 in order to cause axial compression of 42, which as discussed above will inherently result in the radial compression of 42.)

With regards to claim 7, the medical valve includes a distal end (57), the resilient member having a distal end (40), the plug distal end cooperating with the resilient member open distal end to form an internal seal (57 in conjunction with 42).

With regards to claim 8, Purdy et al discloses the internal seal being closed when the resilient member open distal end is occluded by the plug distal end (fig 4).

With regards to claims 13 and 18, Purdy et al discloses a plug member at least in part within a resilient member (bottom legs under 57 are within resilient member 42).

Regarding claim 21, Purdy et discloses the resilient member forces fluid distally toward the distal port when the valve transitions toward the closed mode (when resilient member 42 is pushed down by plug 57 and radially expands, it is inherent that fluid is forced distally and the valve transitions towards a closed mode.)

Claims 1, 7, 8, 10, 13, 14, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Luther (4,842,591).

Luther discloses a medical valve (9) having an open mode to permit fluid flow and a closed mode to prevent fluid flow comprising a body (fig 2) forming an interior (fig 2), a proximal port (31) and a distal port (11), the interior having a fluid channel between the proximal port and the distal port (fig 3) and a valving element (20) within the interior of the body controlling fluid flow between the proximal and distal ports, the valving element including a resilient member (34) and a plug (35), the resilient member forming a variable volume fluid chamber (interior as indicated by the arrows demonstrating fluid flow, it is variable volume because when the resilient member is opened the volume of the interior with fluid is increased) within the interior of the body, the fluid chamber being at least a part of the fluid channel (fig 3), the plug cooperating with the resilient member to provide an internal seal (contact point between the legs of the plug 35 and the resilient member 34) within the interior of the body, the internal seal being spaced from the proximal port (31), the plug being capable of radially expanding the resilient member

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when the valve transitions from the closed mode to the open mode (when resilient member 34 is pushed apart and open, each face as indicated by 34 in figure 3 is expanded radially upon opening), the radial expansion causing the fluid chamber having a larger volume when in the open mode than when in the closed mode, the radial expansion also causing the fluid channel to have a larger volume when in the open mode than when in the closed mode (when resilient member 34 is pushed apart and open, each face as indicated by 34 in figure 3 is expanded radially upon opening, inherently causing the fluid channel to have a larger volume when in the open mode than in the closed mode).

With regards to claims 13 and 18, Luther discloses a plug member at least in part within a resilient member (legs of plug member 35 are within the resilient member 34 when the plug pushes upon the resilient member (see fig 3)).

Regarding claim 21, Luther disclosed the resilient member forces fluid distally toward the distal port when the valve transitions toward the closed mode (when resilient member 34 is pushed apart and open, each face as indicated by 34 in figure 3 is expanded radially upon opening, inherently forcing fluid distally toward the distal port when the valve transitions toward the closed mode).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al in view of Paradis (6,068,011).

Purdy et al discloses the claimed invention as discussed above. However, Purdy et al does not disclose a plug including a plurality of legs that bow outwardly upon the application of a distally directed force and that acts normally bow outwardly, and include leg separator to prevent contact of the legs.

Paradis discloses a plug (20) including a plurality including a plurality of legs (83-1 and 83-2) that bow outwardly upon that application of a distally directed force (abstract, lines 4-7) and that normally bow outwardly (fig 8A), and include a leg separator (legs inside of 83-1 and 83-2) for the purpose of providing a return force to the plug to push it back to its initial position (abstract, lines 4-7).

It would have been obvious to one of ordinary skill in the art to modify the device of Purdy et al by adding a plurality of legs that bow outwardly upon the application of a distally directed force and that normally bow outwardly and include a leg separator from the teaching of Paradis for the purpose of providing a return force to the plug to more effectively push it back to its initial position.

Claims 9 and 17 are rejected under U.S.C. 103(a) as being unpatentable over Purdy et al in view of Paradis (6,168,137).

Purdy et al discloses the claimed invention as discussed above. However, Purdy does not disclose the use of a valve element that is swabbable.

Paradis teaches the use of a swabbable valve element for the purpose of cleansing the valve element (col 2, lines 13-15).

It would have been obvious to one of ordinary skill in the art to modify the device of Purdy et al by using a swabbable valve element in order to cleanse the valve element.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luther. Luther discloses the claimed invention as discussed above. However, Luther does not disclose a split plug member forming at least two portions with separable opposing faces, the opposing faces being substantially flush against each other when in the closed mode.

Luther does disclose a split in the resilient member 34 (see fig 2 and 3) forming at least two portions with separable opposing faces, the opposing faces being substantially flush against each other when in the closed mode.

It would have been obvious to one of ordinary skill in the art to modify the plug 35 and replace permeable membrane of 35 with a split similar to the split in the resilient member in order to permit more efficient fluid flow through the plug.

Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Daugherty et al (5,950,986).

Luther discloses the claimed invention as discussed above. However, Luther does not disclose the use of a proximal seal at the proximal port spaced from an internal seal.

Daugherty teaches the use of a proximal seal (col 4 lines 39-44) that prevents fluid from flowing into areas other than the desired fluid path.

It would have been obvious to one of ordinary skill in the art to modify the valve device of Luther and utilize a proximal seal near the proximal port, which would inherently be spaced from the internal seal since the internal seal is spaced from the proximal port, in order to prevent fluid from permeating regions of the valve into areas outside of the desired flow path prior to the fluid contacting the internal seal.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Daugherty et al and further in view of Paradis.

Luther and Daugherty disclose the claimed invention as discussed above. However, they do not teach the use of a valve element that is swabbable.

Paradis teaches the use of a swabbable valve element for the purpose of cleansing the valve element (col 2 lines 13-15).

It would have been obvious to one of ordinary skill in the art to modify the device of Luther and Daugherty et al by using a swabbable valve element in order to cleanse the valve element.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sivert (4,915,687) discloses a needleless injection port arrangement which demonstrates how a resilient member that is axially compressed will radially expand.

Response to Arguments

6. Applicant's arguments filed 3/16/05 have been fully considered but they are not persuasive. Applicant argues that neither the Purdy or the Luther references show the volumetric relationships of the valves as specified; however, the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of having these relationships, then it meets the claim. Clearly there are no structural differences between the prior art and the claimed invention, and the prior art are capable of having these relationships.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Melissa A McCorkle
Examiner
Art Unit 3763

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9/30/05